



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,918	06/27/2003	John B. Harley	OMRF:050USD2	6316

7590 09/22/2005

Steven L. Highlander
FULBRIGHT & JAWORSKI LLP
600 Congress Avenue Suite 2400
Austin, TX 78701

EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,918

Applicant(s)

HARLEY ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/15/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

39

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5, drawn to a vaccine for preventing autoimmune disorder induced by ENV infection, classified in class 424, subclass 185.1.
 - II. Claims 6-10, and 19-22, drawn to a method for diagnosis test using peptide antigens of EBV, classified in class 435, subclass 5.
 - III. Claims 11-18, drawn to a method of preventing an autoimmune disease induced by EBA infection, classified in class 424, subclass 93.2.
 - IV. Claims 23-25, drawn to a method for screening a therapeutic agent for preventing/treatment of autoimmune disease induced by EBV infection, classified in class 435, subclass 3.
 - V. Claim 26, drawn to a method for screening genetic markers or risk factors for development of autoimmune diseases induced by EBV infection, classified in class 435, subclass 7.1.

If group II is elected one combination of three sequences as listed in claim 8. Because each combination has different sequence structure that requires different search. The inventions of any combination of three peptide sequences are distinct each from other because of the following reasons: The inventions of different groups are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed patentable distinct inventions because each of them has different structurally and functionally that requires different search. For example, the search of sequence of SEQ ID NOs: 1, 2, and 3 in combination is not coextensive to the sequence searches of 7, 13 and 14 in combination or vice-versa.

The inventions of the following groups are also distinct, each from the other because of the following reasons:

2. Inventions of group II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

Art Unit: 1648

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of group II and III are different because they have different modes of operation, different functions, or different effects. For example, the group II is a method of diagnosis involving an enzyme linked immune assay comprising an in vitro test of an antibody and antigen binding assay, whereas the method of group III is a method of treatment involving administration a therapeutic agent in vivo. They are unrelated because they are classified in different classes and require different searches.

3. Inventions of group II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of group II and III are different because they have different modes of operation, different functions, or different effects. For example, the group II is a method of diagnosis involving an enzyme linked immune assay in vitro, whereas the method of group IV is a method for screening a therapeutic agent involving test of a compound in an animal model. They are unrelated because they are classified in different classes and require different searches.

4. Inventions of group II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of group II and V are different because they have different modes of operation, different functions, or different effects. For example, the group II is a method of diagnosis involving an enzyme linked immune assay comprising an in vitro test of an antibody and antigen binding assay, whereas the method of group V is a method for screening a genetic marker or risk factor for development of an autoimmune disease. They are unrelated because they are classified in different classes and require different searches.

5. Inventions of group III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of group IV and III are different because they have different modes of operation, different functions, or different effects. For example, the group IV is a method of is a method for screening a therapeutic agent involving test of a compound in an animal model,

Art Unit: 1648

whereas the method of group III is a method of treatment involving administration a therapeutic agent in vivo. They are unrelated because they are classified in different classes and require different searches.

6. Inventions of group III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of group V and III are different because they have different modes of operation, different functions, or different effects. For example, the group V is a method of is a method for screening a genetic code or marker of an autoimmune disease caused by EBV infection, whereas the method of group III test of a compound in an animal model. They are unrelated because they are classified in different classes and require different searches.

7. Inventions of group IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of group IV and V are different because they have different modes of operation, different functions, or different effects. For example, the group IV is a method of is a method for screening a therapeutic agent involving test of a compound in an animal model, whereas the method of group V is a method for screening a genetic code or marker of an autoimmune disease caused by EBV infection. They are unrelated because they are classified in different classes and require different searches.

8. Inventions of group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such as diagnosis of EBV infection rather than a treatment.

9. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II or group II is not required for group IV or V, restriction for examination purposes as indicated is proper.

Art Unit: 1648

10. Claims 15 is generic to a plurality of disclosed patentably distinct species comprising 1). systemic lupus erythematosus, 2). Sjogren's syndrome, 3). rheumatoid arthritis, 4). juvenile onset diabetes mellitus, 4). Wegener's granulomatosis, 5). inflammatory bowel disease, 6). Polymyositis dermatomyositis, 7). multiple endocrine failure, 8). Schmidt's syndrome, autoimmune uveitis, 9). Addison's disease, 10). adrenalitis, 11). primary biliary cirrhosis, 12). Graves' disease, 13). thyroiditis, 14). Hashimoto's thyroiditis, 15). autoimmune thyroid disease, 16). pernicious anemia, 17). lupoid hepatitis, 18). Demyelating diseases, 19). multiple sclerosis, 20). subacute cutaneous lupus erythematosus, 21). hypoparathyroidism, 22). Dressler's syndrome, 23). myasthenia gravis, 24). autoimmune thrombocytopenia, 25). idiopathic. 26). thrombocytopenic purpura, 27). hemolytic anemia, 28). autoimmune hemolytic anemia, 29). pemphigus vulgaris, 30). pemphigus, 31). bullous pemphigoid, 32). dermatitis herpetiformis, alopecia areata, 33). autoimmune cystitis, 34). pemphigoid, 35). scleroderma, 36). progressive systemic sclerosis, 37). CREST syndrome (calcinosis, Raynaud's esophageal dysmotility, sclerodactyly, and telangiectasia), 38). adult onset diabetes mellitus (Type 1 diabetes), 39). male or female autoimmune infertility, 40). ankylosing spondylitis, 41). ulcerative colitis, 42). Crohn's disease, 43). mixed connective tissue disease, 44). polyarteritis nodosa, 45). systemic necrotizing vasculitis, 46). juvenile onset rheumatoid arthritis, 47). glomerulonephritis, 48). Atopic dermatitis, 49). atopic rhinitis, 50). Goodpasture's syndrome, 51). Chagas' disease, 52). sarcoidosis, 53). Rheumatic fever, 54). asthma, recurrent abortion, 55). anti-phospholipid syndrome, 56). farmer's lung, 57). erythema multiforme, 58). postcardotomy syndrome, 59). Cushing's syndrome, 60). autoimmune chronic active hepatitis, 61). bird-fancier's lung, 62). allergic encephalomyelitis, 63). toxic necrodermal lysis, 64). alopecia, 65). Alport's syndrome, alveolitis, 66). allergic alveolitis, 67). fibrosing alveolitis, 68). interstitial lung disease, 69). erythema nodosum, 70). pyoderma gangrenosum, 71). transfusion reaction, 72). chronic fatigue syndrome, 73). fibromyalgia, 74). Takayasu's arteritis, 75). Kawasaki's disease, 76). polymyalgia rheumatica, 77). temporal arteritis, 78). giant cell arteritis, 79). Sampter's syndrome (triaditis also called, nasal polyps, 80). eosinophilia, 81). Asthma, 82). Behcet's disease, 84). Caplan's syndrome, 85). dengue, 86). encephalomyositis, 87). Endocarditis, 89). myocarditis, 90). endomyocardial fibrosis, 91). endophthalmitis, 92). erythema elevatum et diutinum, 93). psoriasis, 94). erythroblastosis fetalis, 95). fascitis with eosinophilia, 96). Shulman's syndrome,

Art Unit: 1648

97). Felty's syndrome, 98). tilariasis, 99). cyclitis, 100). chronic cyclitis, 101). heterochromic cyclitis, 102). Fuch's cyclitis, 103). IgA nephropathy, 104). Henoch-schonlein purpura, 105). glomerulonephritis, ' cardiomyopathy, 106). post vaccination syndromes, 107). Hodgkin's and non-Hodgkin's lymphoma, 108). renal cell carcinoma, 109). Eaton-Lambert syndrome, 110). relapsing polychondritis.

11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAOQUN LI, M.D.
PATENT EXAMINER

Baoqun Li

Bao Qun Li

09/19/2005